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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,365	12/30/1999	DR. PORUNELLOR A. MATHEW	91561/74891	6249

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/13/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/475,365

Applicant(s)

MATHEW ET AL.

Examiner

Ruixiang Li

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 16 on November 6, 2002 has been entered in full. Claims 1 and 7 have been amended. Claims 1-21 are pending. Claims 1-12 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Withdrawn Objections and/or Rejections**

The objection to the Disclosure, as set forth at page 2 of the previous Office Action (Paper No. 15, May 6, 2002) has been withdrawn in view of applicants' amendment to the specification.

The rejection of claims 7-10 under 35 U.S.C. 101, as set forth at page 3 of the previous Office Action (Item # 6 of Paper No. 8, January 25, 2002), has been withdrawn in view of applicants' amendment to claim 7.

The rejection of claims 1 and 7 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as set forth at page 7 of the previous Office Action (Paper No. 15, May 6, 2002), has been withdrawn in view of applicants' amendment to the claim.

The rejection of claims 1-12 under 35 U.S.C. 102 (b), as set forth at page 7-8 of the previous Office Action (Paper No. 15, May 6, 2002), has been withdrawn in view of applicants' argument about the effective filing date of the current application.

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### **III. Objections to Drawings**

The objection to drawings, Figs. 1-4, remains. It is noted that a proposed drawing correction or corrected drawings have not been submitted to the office. Applicants are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### **IV. 35 U.S.C. § 101**

(i) The rejection of claims 1-6, 11, and 12 under 35 U.S.C. 101, as set forth at page 3 of the previous Office Action (Paper No. 15, May 6, 2002), remains.

Claims 1-6, 11, and 12 are rejected because the claims read on product of nature. It is suggested that the polypeptide is modified by the word "isolated" and modified with a SEQ ID NO.

(ii) The rejection of claims 1-12 under 35 U.S.C. 101, as set forth at pages 3-5 of the previous Office Action (Paper No. 15, May 6, 2002), remains. Claims 1-12 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility.

Applicants argue (i) that the putative lectin-like receptor or LLT1 shares sequence homology with CD69 and AICL, two members of the C-type lectin superfamily; (ii) that the expression of LLT1 corresponds to NK cells, as would be expected of a member of the C-lectin superfamily of receptors, and is localized in the NK gene complex of chromosome 12; and (iii) LLT1 is a member of the C-lectin superfamily of receptor, having a utility in the activation of lymphoid tissue, much like CD69 (page 3).

Applicants' argument has been fully considered but is not deemed to be persuasive for the following reasons. While the C-type lectin superfamily has a well-established utility, the sequence homology of LLT1 with CD69, a member of the C-type lectin superfamily LLT1, does not endow the claimed molecules with a specific and substantial utility in view of the diversity of the structure and functions of proteins of C-type lectin family (Weis et al. The C-type lectin superfamily in the immune system. Immunol. Rev. 163:19-34, 1998). The sequence homology of LLD1 with CD69 is only 56%, there is no evidence on whether LLT1 would actually function like CD69 or AICL. The instant disclosure fails to provide reasonably convincing information on the biological functions of LLT1. Any prediction of biological functions of LLT1 based upon sequence analysis would ultimately required to be confirmed by significant further experimentation, which is not acceptable under 35 USC §101.

**V. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph**

The rejection of claims 1-12 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, as set forth at 5-6 of the previous Office Action (Paper No. 15, May 6, 2002), remains. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth at pages 3-6 of the previous Office Action (Paper No. 15, May 6, 2002).

The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reasons set forth above.

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The rejection of claims 1, 2, and 4-11 due to scope of enablement issue remains.

Applicants argue that the amended claim 1 recites a LLT1 receptor and applicants have provided the sequence of LLT1 in Figure1, thereby satisfying the USPTO enablement guidelines and teaching how to make and use at least one embodiment of the claims without undue experimentation (4<sup>th</sup> paragraph of page 4 of applicants' response). This has been fully considered but is not deemed to be persuasive because even if the claimed receptor with the amino acid sequence set forth in SEQ ID NO: 2 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed variants of SEQ ID NO:2. The Examiner notes that the instant specification does teach how to make SEQ ID NO:2. That is why a scope enablement rejection was made in the previous office action. The Examiner also notes that claim 1, as written, only recites LLT1, but fails to recite SEQ ID NO: 2 in the claim.

Applicants argue that applicants have shown that the sequence shown in Figure 1 and comparison of that sequence to other C-type lectin superfamily receptors (Figure 2), as well as examples 1-6 walk through the procedure for cloning and characterizing the LLT1 receptor, indicating the importance and function of particular amino acid motifs (bottom of page 4 of applicants' response). This has been fully considered but is not deemed to be persuasive because while the disclosure would enable SEQ ID NO:2 (if a patentable utility were found), it would not enable all the variants as instantly claimed. Due to lack of a defined biological function, the instant disclosure consequently fails to identify which amino acid residues critical to the activity or functions of SEQ ID NO:2.

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Applicants argue that one of skill in the art would be able to practice the invention since applicants have provided information about the structure of LLT1 receptor and motifs of the LLT1 receptor; parameters used to identify the similarity of the LLT1 receptor to other C-type lectin membrane; working examples on the characterization of LLT1 receptor; and the level of skill in the art is high (top of page 5 of applicants response). This has been fully considered but is not deemed to be persuasive because other than the making of SEQ ID NO: 2, the disclosure fails to provide sufficient information or working examples on how to produce and use the variants of the claimed receptor of SEQ ID NO: 2. While the level of skill in the art related to C-type lectin proteins is high, without defined biological function of LLT1, one skilled in the art would not be able to make functional variants of SEQ ID NO:2 without undue experimentation.

#### **VI. Claim Rejections Under 35 U. S. C. § 112, 2<sup>nd</sup> Paragraph**

The rejection of claims 8-10 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph as set forth at page 7 of the previous Office Action (Paper No. 15, May 6, 2002) remains.

Applicants argue that the problematic language in the claims has been corrected thereby overcoming the §112, second paragraph rejection. This has been fully considered but is not found to be persuasive because claims 8-10 have not been amended to clarify whether these claims are directed to a polypeptide or a pharmaceutical composition comprising the polypeptide.

Claim 12 is indefinite because it refers to the sequence in a figure. The sequence should be given a SEQ ID NO in the claim.

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## **VII. Claim Rejections Under 35 U. S. C. § 102 (a)**

The rejection of claims 1-12 under 35 U. S. C. § 102 (b) as set forth at page 7 of the previous Office Action (Paper No. 15, May 6, 2002) has been replaced by the following rejection of claims 1-12 under 35 U. S. C. § 102 (a), which reflects correction of an error on the filing date of the current application in the office's record.

(i) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(ii) Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Boles et al.

(*Immunogenetics* 50:1-7, October of 1999).

Boles et al. teach a new lectin-like receptor expressed on human NK cells, LLT1, which is exactly the same as the claimed natural killer cell receptor polypeptide (See, e.g., Abstract; Figs. 1 and 2), meeting all the limitations of claims 1-12.

## **VIII. Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282.

The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

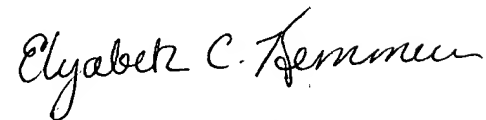
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



ELIZABETH KEMMERER  
PRIMARY EXAMINER

Ruixiang Li  
Examiner  
January 8, 2003